UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: 03-APR-2017

Subject: **Glufosinate Ammonium.** Canola, Corn (Field and Sweet), and Soybean Label Amendment and Pistachio FIFRA 6(a)(2) Data. Abbreviated Residue Chemistry Review.

PC Code: 128850
Decision No.: 519449
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: See Table A

DP Barcode: D437605
Registration No.: NA
Regulatory Action: Label Amendment
Case No.: 7224
CAS No.: 77182-82-2
40 CFR: 180.473

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Table A. MRID Summary Table For Glufosinate Ammonium Label Amendment & Pistachio 6a2 Data

MRID No.	Study Type	Comments
49963401	860.1500 soybean trials	49963401.der.docx
49963402	860.1500 field corn trials	49963402.der.docx
49963403	860.1520 soybean processing study	49963403.der.docx
49974601	860.1500 pistachio field trials	49974601.der.docx

Background

Glufosinate ammonium [butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt] is used as a non-selective herbicide for total vegetation control and as a desiccant to aid in crop harvesting. Glufosinate ammonium is currently registered for food/feed uses on many agricultural crops: conventional (limited to preplant/preemergent uses) and genetically modified (glufosinate tolerant for in-season applications).

Bayer CropScience (BCS) has requested a label amendment to increase the application rates for the following crops, which include both the conventional and LibertyLink™ (LL) varieties: canola, field corn, sweet corn, and soybean. In support of this request, BCS submitted field trial data for field corn and soybean reflecting the new application rates. For canola and sweet corn, BCS cites previously reviewed field trial data, noting that the new rates are within 25% of the rates used in the previously reviewed magnitude of the residue studies. Although the glufosinate ammonium residue chemistry database includes adequate processing studies for soybean and corn, BCS submitted the results of a new soybean processing study but not for corn. In addition, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 6(a)(2) information, BCS has submitted field trial data for pistachios that show residues higher than the established tree nut tolerance at two trial locations (out of six tested). These data are considered in this memo, which summarizes the regulatory conclusions pertaining to all the new residue chemistry data submitted. The current memo is limited to those guideline topics relevant to the label amendment and review of the 6(a)(2) pistachio data; as such the current memo is an abbreviated review.

BCS did not propose any tolerance increases to support the current actions, asserting that the established tolerances are adequate to cover the new use patterns. As part of the present review, HED has analyzed the new data using Organisation for Economic Co-operation and Development (OECD) maximum residue limit (MRL) calculation procedures, and compared the results to established tolerances. Additionally, international harmonization considerations were included in the tolerance recommendations presented.

Conclusions

Provided that the registrant submits a Section F for the increased tolerance levels identified, there are no residue chemistry considerations that would preclude approval of the requested label amendments to the use patterns for canola, field corn, sweet corn, and soybean. Recommended tolerance increases include: 1) soybean hulls to 10 ppm as a result of a new soybean processing study, 2) tree nut group 14-12 to 0.50 ppm as a result of review of the pistachio 6(a)(2) data, and 3) canola seed to 3.0 ppm for international harmonization. The current tolerance expression for glufosinate ammonium (40 CFR §180.473) correctly reads as follows:

> "Tolerances are established for residues of glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring the sum of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl) monoammonium salt) and its

metabolites, 2-(acetylamino)-4-(hydroxymethyl phosphinyl) butanoic acid, and 3-(hydroxymethylphosphinyl) propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents."

Table 1. Glufosinate Ammonium Tolerance Reassessment for Label Amendment Crops (Canola, Corn, and Soybean) and Pistachio.

Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments *Correct Commodity Definition*
Canola, meal	1.1	--	
Canola, seed	0.40	3.0	Harmonization purposes
Corn, field, forage	4.0	4.0	
Corn, field, grain	0.20	0.20	
Corn, field, stover	6.0	6.0	
Corn, sweet, forage	1.5	1.5	
Corn, sweet, K+CWHR	0.30	0.30	
Corn, sweet, stover	6.0	6.0	
Soybean, hulls	5.0	10	New soybean processing study
Soybean	2.0	2.0	*Soybean, seed*
Nut, tree, group 14	0.10	0.50	New pistachio data under 6(a)(2) *Nut, tree, group 14-12*

Note to RD: The current tolerance of 0.05 ppm for apple should be revoked as this commodity is included in the fruit, pome, group 11-10 tolerance. Also, the current tolerance of 0.10 ppm for pistachio should be revoked as this commodity will be included in the nut, tree, group 14-12 tolerance. Finally, upon increasing the canola, seed tolerance to 3.0 ppm, the canola meal tolerance should be deleted as any residues in this commodity will be covered by the seed tolerance. See Appendix A for a listing of chemical structures and names for glufosinate ammonium and its regulated metabolites.

A human-health risk assessment is forthcoming.

Detailed Considerations

Pesticide Use Pattern/Directions for Use

Table 2 provides a summary of the proposed use directions for glufosinate ammonium on LibertyLink™ (LL) soybean, canola, field corn and sweet corn. The submitted field trials for soybean and field corn reflect the maximum application rates and follow the proposed label directions.

Table 2. Summary of Directions for Proposed Uses of Glufosinate.

Application Equipment	Formulation / Product [EPA Reg. No.] / Percent AI	Max Single Application Rate	Max App Rate per Year[1]	PHI (days)	Use Directions and Limitations
LL Soybean					
Burndown treatment (prior to planting or prior to emergence of crop) Aerial and Groundboom	Liquid [264-829] 24.5% ai 2.34 lb ai/gal	1 x 0.53 - 0.79 lb ai/A	1.59 lb ai/A	NA	Chemigation prohibited For in season apps - RTI = 5 days
In-season application Aerial or Groundboom		2 x 0.79 lb ai/A		70	
LL Canola					
Burndown treatment (prior to planting or prior to emergence of crop) Aerial and Groundboom	Liquid [264-829] 24.5% ai 2.34 lb ai/gal	1 x 0.53 - 0.79 lb ai/A	1.59 lb ai/A	NA	Chemigation prohibited For in season apps - RTI = 7 days
In-season application Aerial or Groundboom		2 x 0.53 lb ai/A[1]		65	
LL Field corn					
Burndown treatment (prior to planting or prior to emergence of crop) Aerial and Groundboom	Liquid [264-829] 24.5% ai 2.34 lb ai/gal	1 x 0.53 - 0.79 lb ai/A	1.59 lb ai/A	NA	Chemigation prohibited For in season apps - RTI = 7 days
In-season application Aerial or Groundboom		2 x 0.79 lb ai/A		70	
LL Sweet corn					
Burndown treatment (prior to planting or prior to emergence of crop) Aerial and Groundboom	Liquid [264-829] 24.5% ai 2.34 lb ai/gal	None	0.80 lb aiA	NA	Chemigation prohibited For in season apps - RTI = 7 days
In-season application Aerial or Groundboom		2 x 0.40 lb ai/A		50 for sweet corn ears and 55 for stover	

[1] Sum of burndown and in-season applications.
[2] For canola seed propagation, up to three in season applications at 0.53 lb ai/A are allowed.

In order to properly evaluate the suitability of the residue data submitted and the registrant's rationale for relying on previously reviewed data for certain crops, a comparison of current and proposed application rates is instructive. Table 3 provides this comparison for both the

conventional and LL crops indicated. Because no postemergence uses are allowed for conventional crops, the remainder of this memo focuses on the LL crop uses.

Table 3. Comparison of Current and Proposed Use Patterns for Glufosinate Ammonium.

	Current Rates (lb ai/A)			Proposed Rates (lb ai/A)		
Crop	Burndown	In-Season	Max. Yearly	Burndown	In-Season	Max. Yearly
Conventional Canola Conventional Soybean Conventional Field Corn Conventional Sweet Corn	0.53-0.66	None	0.66	0.53-0.79	None	0.79
LL Canola	None	2 x 0.40	0.80	0.53-0.79	2 x 0 53	1.59
LL Canola for Seed Propagation	None	3 x 0.40	1.20	None	3 x 0.53	1.59
LL Soybean	0.53-0.66	1 x 0.53	1.19	0.53-0.79	2 x 0.53-0.79	1.59
LL Field Corn	None	2 x 0.40	0.80	0.53-0.79	2 x 0 53-0.79	1.59
LL Sweet Corn	None	2 x 0.365	0.73	None	2 x 0.40	0.80

Conclusions
The proposed use directions are adequate to allow evaluation of the submitted residue data. No label changes are needed.

Residue Analytical Method

Samples of soybean, corn, and pistachio were analyzed for residues of glufosinate, glufosinate propanoic acid, and N-acetylglufosinate using LC/MS/MS Method No. GL-006-P11-01. The method is based on Method No. GL-001-P07-01 which was previously used for data collection in transgenic canola seed studies (D409526, W. Donovan, 25-JUL-2013). Method modifications included use of cold water/methanol instead of water for initial extraction and changes to the LC/MS/MS conditions and the ion transitions that were monitored.

The modified method monitors the following ion transitions for determination of glufosinate and metabolites and the corresponding internal standards (IS), respectively:

Glufosinate and IS: *m/z* 179.7 → 62.9 and *m/z* 182.7 → 62.9
Glufosinate propanoic acid and IS: *m/z* 153.0 → 135.0 and *m/z* 156.0 → 138.0
N-acetylglufosinate and IS: *m/z* 224.2 → 177.9 and *m/z* 227.2 → 120.9

Method validation and concurrent recoveries reported in support of the field trial studies were within the acceptable range of 70-110%, with a relative standard deviation of less than 10%. This method validation work was conducted at the lowest level of method validation (LLMV) and higher concentrations sufficient to support the range of residues found in the field trial studies. HED concludes that LC/MS/MS Method No. GL-006-P11-01 is adequate for data collection purposes.

Storage Stability

Table 4. Summary of Sample Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Corn forage	≤-18	256-353 days (8.4-11.6 months)	Residues of glufosinate ammonium, glufosinate propanoic acid, and N-acetylglufosinate are stable for at least 24 months in transgenic field corn grain and forage; and for at least 26 months in sweet corn forage and at least 30 months in sweet corn ears.[2]
Corn grain		200-314 days (6.6-10.3 months)	
Corn stover		214-313 days (7.0-10.3 months)	
Soybean seed	~-20	175-298 days (5.7-9.8 months)	Residues of glufosinate ammonium, glufosinate propanoic acid, and N-acetylglufosinate are stable for at least 24 months in transgenic soybean seed and hay.[2]
Pistachio nutmeat		544 days (18 months)	

[1] Interval from harvest to extraction. Samples were analyzed within 6 days of extraction.
[2] Pesticide Residues in Food 2012 – Joint FAO/WHO Meeting on Pesticide Residues, pg 223.

Corn

The maximum storage intervals for samples from harvest to extraction for analysis were 11.6 months for forage, and 10.3 months for grain and stover (Table 4). Samples were analyzed within 3 days of extraction. Acceptable storage stability data are available indicating that residues of glufosinate ammonium, glufosinate propanoic acid, and N-acetylglufosinate are stable for at least 24 months in transgenic field corn grain and forage (Pesticide Residues in Food 2012 – Joint FAO/WHO Meeting on Pesticide Residues, pg. 223). Thus, the available storage stability data are adequate to support the sample storage conditions and durations from the submitted study.

Pistachio

The maximum storage interval for samples from harvest to extraction for analysis was 18 months (Table 4). Acceptable storage stability data are available indicating that residues of glufosinate ammonium, glufosinate propanoic acid, and N-acetylglufosinate are stable for at least 24 months in transgenic soybean seed and hay (Pesticide Residues in Food 2012 – Joint FAO/WHO Meeting on Pesticide Residues, pg. 223). The storage stability results on soybean may be translated to cover the storage intervals incurred in the submitted pistachio magnitude of the residue study.

Soybean

The maximum storage interval for samples from harvest to extraction for analysis was 9.8 months (Table 4). Samples were analyzed within 6 days of extraction. Acceptable storage stability data are available indicating that residues of glufosinate ammonium, glufosinate propanoic acid, and N-acetylglufosinate are stable for at least 24 months in transgenic soybean seed and hay (Pesticide Residues in Food 2012 – Joint FAO/WHO Meeting on Pesticide Residues, pg. 223). The available data are adequate to support the sample storage conditions and durations from the submitted study.

Crop Field Trials

Table 5 provides a comparison of the proposed use pattern for glufosinate ammonium on LL canola, soybean, field corn and sweet corn with use patterns followed in the supporting field trial studies.

Table 5. Comparison of the proposed use pattern with that followed in crop field trial studies.

Crop[1]	Proposed Use Pattern (lb ai/A)				Crop Field Trial Data					MRID Reference
	Burn-down	In season	Yearly	Timing	Rate (lb ai/A)	Apps	Total (lb ai/A)	PHI (days)	RTI (days)	
LL Canola	0.53-0.79	2 x 0.53	1.59	65-day PHI	0.44	1: BBCH 12-14; 2: BBCH 15-18; 3: BBCH 18-30	1.33	~60	~7	48976701 48976703
LL Soybean	0.53-0.79	2 x 0.53-0.79	1.59	R1/bloom Seed=70 day PHI	0.80	1: BBCH 13-14; 2: BBCH 14-16	1.60	~100	~7	49963401
LL Field corn	0.53-0.79	2 x 0.53-0.79	1.59	V6 Forage=60 day PHI Grain, stover= 70 day PHI	1: 1.05 2: 0.55	1: BBCH 13-14; 2: BBCH 16-19	1.60	~110	~10	49963402
LL Sweet corn	0.53-0.79	2 x 0.40	0.80	V6 Ears=50 day PHI Stover=55 day PHI	0.375	1: Not specified; 2: Not specified	0.75	45	14	47828202

[1] LL refers to LibertyLink™ modified crop. For conventional (i.e., unmodified) canola, corn (field and sweet), and soybean, only burndown uses prior to planting or emergence are allowed. The proposed application rate for burndown uses for the conventional crops is 0.53 – 0.79 lb ai/A. This represents an increase of 20% above current burndown use rates of 0.53 – 0.66 lb ai/A.

New residue data were submitted for soybean and field corn since the proposed maximum yearly use rate exceeded the current rate (or rate used in previously conducted residue trials) by more than 25%. For canola and sweet corn, the proposed rate represents less than a 25% increase and thus, reference was made to previously-reviewed data.

Canola

The maximum proposed yearly application rate for canola (1.59 lb ai/A) represents a 20% increase from the corresponding rate used in the field trial data (1.33 lb ai/A) previously reviewed (D409526, W. Donovan, 25-JUL-2013). HED has no objection to the proposed rate since it is within 25% of the rate used in the eight canola trials previously reviewed (48976701.der.docx), and in light of the results of the canola processing study (MRID 48976702) where two trials treated at an exaggerated rate of 5X (6.6 lb ai/A) showed no detectable residues of glufosinate ammonium nor its regulated metabolites.

Field Corn

In support of the increased use rate proposed for transgenic field corn, the registrant submitted the results of 18 trials conducted in the U.S. (see 49963402.der.docx). Each trial consisted of one untreated plot and two treated plots reflecting foliar broadcast application of glufosinate ammonium (Liberty 280 SL) as a single application at BBCH 14-16 (growth stages V4-V5; TRTD1), or as two applications, with the first made at BBCH 13-14 (growth stages V3-V4) and the second made at BBCH 17-19 or 37 (growth stage V7) at retreatment intervals (RTIs) of 7-13

days (TRTD2). Application rates were: 1.5-1.6 lb ai/A for TRTD1; and 1.0-1.1 lb ai/A for the first application and 0.52-0.55 lb ai/A for the second application for total rates of 1.6 lb ai/A for TRTD2. Results were reported for corn grain, forage, and stover as summarized in Table 6.

Table 6. Summary of Residues from Field Corn Field Trials with Glufosinate Ammonium.

TRT Plot[1]	Total Application Rate (lb ai/A) [kg ai/ha]	Analyte	PHI (days)	n[2]	Residues, Glufosinate Equivalents (ppm)						
					Min.[3]	Max.[3]	LAFT[4]	HAFT[4]	Median[4]	Mean[4]	SD[4]
Field corn forage											
TRTD1	1.5-1.6 [1.7-1.8]	Glufosinate	59-89	18	<0.01	0.257	<0.01	0.211	0.01	0.028	0.047
		Glufosinate propanoic acid			<0.01	0.148	<0.01	0.125	0.025	0.043	0.041
		N-acetylglufosinate			<0.01	0.981	<0.01	0.849	0.040	0.115	0.203
		Combined[5]			<0.040	1.34	<0.044	1.18	0.099	0.186	0.267
TRTD2	1.6 [1.8]	Glufosinate	30-82	18	<0.01	0.257	<0.01	0.232	0.036	0.059	0.068
		Glufosinate propanoic acid			<0.01	0.229	<0.01	0.189	0.031	0.055	0.056
		N-acetylglufosinate			0.013	1.08	0.014	1.04	0.179	0.271	0.317
		Combined[5]			<0.033	1.48	<0.034	1.42	0.272	0.386	0.407
Field corn grain											
TRTD1	1.5-1.6 [1.7-1.8]	Glufosinate	100-133	18	<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
		Glufosinate propanoic acid			<0.01	0.046	<0.01	0.039	0.01	0.015	0.010
		N-acetylglufosinate			<0.01	0.016	<0.01	0.016	0.01	0.010	0.001
		Combined[5]			<0.03	<0.066	<0.03	<0.059	0.03	0.035	0.010
TRTD2	1.6 [1.8]	Glufosinate	71-126	18	<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
		Glufosinate propanoic acid			<0.01	0.045	<0.01	0.044	0.01	0.016	0.012
		N-acetylglufosinate			<0.01	0.031	<0.01	0.030	0.01	0.012	0.005
		Combined[5]			<0.03	<0.069	<0.03	<0.068	0.03	0.038	0.013
Field corn stover											
TRTD1	1.5-1.6 [1.7-1.8]	Glufosinate	100-133	18	<0.01	0.270	<0.01	0.248	0.011	0.044	0.066
		Glufosinate propanoic acid			<0.01	0.349	<0.012	0.319	0.078	0.113	0.101
		N-acetylglufosinate			<0.01	0.706	<0.01	0.695	0.029	0.107	0.185
		Combined[5]			<0.034	0.972	<0.040	0.911	0.160	0.264	0.280
TRTD2	1.6 [1.8]	Glufosinate)	71-126	18	<0.01	0.839	<0.01	0.760	0.043	0.116	0.179
		Glufosinate propanoic acid			<0.01	0.549	<0.01	0.537	0.132	0.186	0.167
		N-acetylglufosinate			<0.01	3.20	<0.010	2.90	0.074	0.294	0.663
		Combined[5]			<0.03	4.30	<0.030	3.92	0.343	0.596	0.893

[1] TRTD1 = single application at BBCH 14-16; TRTD2 = two applications with the first made at BBCH 13-14 and the second made at BBCH 16-19 or 37.
[2] n = number of field trials.
[3] Values based on residues in individual samples.
[4] Values based on per-trial averages. LAFT = lowest average field trial, HAFT = highest average field trial, SD = standard deviation. For computation of the LAFT, HAFT, median, mean, and standard deviation, values <LOQ are assumed to be at the LOQ (0.01 ppm). N/A = Not applicable
[5] Combined residues of glufosinate, glufosinate propanoic acid, and N-acetylglufosinate.

Analyzing these data using the OECD MRL calculator results in a recommended MRLs of 0.1, 3,

and 5 ppm, for grain, forage, and stover, respectively (see Appendix C). As these levels are less than the established tolerances of 0.2, 4.0, and 6.0 ppm, HED concludes that there is no need for changes to the field corn tolerances as a result of the increased use rate proposed for field corn.

Soybean

In support of the increased use rate proposed for transgenic soybean, the registrant submitted the results of 21 trials conducted in the U.S. and Canada (see 49963401.der.docx). Each trial consisted of one untreated plot and treated plots reflecting foliar broadcast application of glufosinate ammonium (Liberty 280 SL) as: a single application made during BBCH 13 and no later than the start of BBCH 14 (second to third trifoliate; TRTD1); or two applications, with the first made at approximately BBCH 13 or 14 and the second made at a RTI of 4-7 days and at approximately BBCH 15 (fourth trifoliate) but before bloom (BBCH 51; TRTD3). Application rates were: 1.5-1.7 lb ai/A for TRTD1; and 0.76-0.82 lb ai/A/application for a total rate of 1.6 lb ai/A for TRTD3. Results were only reported for seed as there is a labeled feeding restriction against forage and hay, see Table 7.

Table 7. Summary of Residues from Soybean Field Trials with Glufosinate Ammonium.

TRT Plot[1]	Total Application Rate (lb ai/A) [kg ai/ha]	Analyte	PHI (days)	n[2]	Residues, Glufosinate Equivalents (ppm)						
					Min.[3]	Max.[3]	LAFT[4]	HAFT[4]	Median[4]	Mean[4]	SD[4]
Soybean seed											
TRTD1	1.5-1.7 [1.7-1.9]	Glufosinate	91-141	21	<0.01	0.016	<0.01	0.016	0.01	0.010	0.001
		Glufosinate propanoic acid			<0.01	0.209	<0.01	0.178	0.075	0.070	0.053
		N-acetylglufosinate			0.011	0.354	0.012	0.331	0.091	0.106	0.076
		Combined[5]			<0.031	0.446	<0.032	0.426	0.185	0.186	0.107
TRTD3	1.6 [1.8]	Glufosinate	86-134	21	<0.01	0.037	<0.01	0.037	0.01	0.016	0.009
		Glufosinate propanoic acid			<0.01	0.191	<0.01	0.185	0.050	0.071	0.056
		N-acetylglufosinate			0.030	1.13	0.033	1.10	0.181	0.301	0.277
		Combined[5]			<0.055	1.30	<0.057	1.27	0.257	0.387	0.326

[1] TRTD1 = single application at BBCH 13-14; TRTD3 = two applications with the first made at BBCH 13-14 and the second made at an RTI of 4-7 days at BBCH 14-16.
[2] n = number of field trials.
[3] Values based on residues in individual samples.
[4] Values based on per-trial averages. LAFT = lowest average field trial, HAFT = highest average field trial, SD = standard deviation. For computation of the LAFT, HAFT, median, mean, and standard deviation, values <LOQ are assumed to be at the LOQ (0.01 ppm).
[5] Combined residues of glufosinate, glufosinate propanoic acid, and N-acetylglufosinate.

Analyzing these data using the OECD MRL calculator results in a recommended MRL of 2 ppm (see Appendix C), consistent with the established tolerance of 2.0 ppm. HED concludes that the established tolerance level for soybean seed is adequate to support the proposed label amendment.

Sweet Corn

The proposed maximum yearly application rate for sweet corn (0.80 lb ai/A) represents a 7% increase from the corresponding rate used in the field trial data (0.75 lb ai/A) previously reviewed (D372625, I. Negrón-Encarnación, 31-AUG-2010; 47828202.der.docx). HED has no

objection to the proposed rate since it is well within 25% of the rate used in the sweet corn field trial studies.

Pistachio

Pursuant to Section 6(a)(2) of FIFRA, BCS submitted the results of 6 field trials conducted in CA depicting glufosinate ammonium residues in pistachio. In two of the trials, residues were higher than the current tree nut tolerance of 0.1 ppm (see 49974601.der.docx). Results were reported for pistachio nutmeat as summarized in Table 8. Because residues increased slightly with increasing PHI up to 21 days, the highest residues from each trial were selected for analysis using MRL calculation procedures, which resulted in a recommended MRL of 0.5 ppm (see Appendix C). Accordingly, HED recommends that the current tolerance level of 0.1 ppm for crop group 14 be increased to 0.50 ppm for crop group 14-12.

Table 8. Summary of Residues from Pistachio Field Trials with Glufosinate Ammonium.

Crop Matrix	Analyte	Total Application Rate (lbs ai/A) [kg ai/ha]	PHI (days)	n	Residues, Glufosinate Equivalents[1] (ppm)						
					Min.[2]	Max.[2]	LAFT[3]	HAFT[3]	Median[3]	Mean[3]	SD[3]
Pistachio											
Nutmeat	Glufosinate	4.5 [5.0]	14	6	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	NA
	Glufosinate propanoic acid				<0.01	0.231	<0.01	0.210	0.036	0.076	0.086
	N-acetylglufosinate				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	NA
	Combined				<0.03	0.25	<0.03	0.23	0.056	0.097	0.088

[1] Expressed as parent equivalents.
[2] Values based on total number of samples.
[3] Values based on per-trial averages. LAFT = lowest average field trial, HAFT = highest average field trial, SD = standard deviation. For computation of the LAFT, HAFT, median, mean, and standard deviation, values < LOQ are assumed to be at the LOQ (0.010 ppm).
n = number of field trials.

Conclusions

Adequate field trial data are available to support the requested label rate increases for canola, field corn, sweet corn and soybean. Further, as required by FIFRA 6(a)(2), pistachio field trial data were reported and evaluated. Data from the trials are representative of maximum residues expected to result from application of glufosinate ammonium according to proposed use patterns, and the residue data were collected using a validated analytical method. Adequate storage stability data demonstrated residue stability for the sample storage times incurred during the field trials. Analysis of the results using OECD MRL calculation procedures demonstrates that established tolerance levels for the RACs from corn, soybean, and canola are appropriate but the tree nut tolerance should be increased to 0.50 ppm.

Processed Food/Feed

49963403.der.docx

Soybean

BCS submitted the results of a new soybean processing study, reflecting an exaggerated rate treatment of 5X (see 49963403.der.docx). Residues were found to concentrate in hulls but not in meal or oil. Table 9 summarizes the study results, which are consistent with the theoretical concentration factor based on separation into components for soybean hulls (11.3X) listed in

Table 3 of OCSPP 860.1520 Guidelines. Most of the hull residue is from glufosinate propanoic acid, for which a processing factor of 11.3x was determined. As this value matches the theoretical factor, HED considers it appropriate for use in determining the tolerance level for soybean hulls.

Table 9. Residue Data from Soybean Processing Study with Glufosinate Ammonium.

Commodity	Analyte	Residues[1] (ppm)[Average]	Processing Factor[2]	Median Processing Factor[3]
Soybean seed (RAC)	Glufosinate	0.1344, 0.1213, 0.1098 [0.122]	--	--
	Glufosinate propanoic acid	2.660, 2.891, 3.065 [2.87]	--	--
	N-acetylglufosinate	0.9380, 0.8399, 0.8662 [0.881]	--	--
Hulls	Glufosinate	2.823, 1.904, 1.446 [2.06]	16.9x	Not Applicable
	Glufosinate propanoic acid	37.52, 29.46, 30.58 [32.5]	11.3x	
	N-acetylglufosinate	11.01, 8.696, 8.479 [9.39]	10.7x	
Meal	Glufosinate	<0.050, <0.050, <0.050 [<0.050]	<0.4	
	Glufosinate propanoic acid	<0.050, <0.050, <0.050 [<0.050]	<0.1	
	N-acetylglufosinate	<0.050, <0.050, <0.050 [<0.050]	<0.1	
Refined oil	Glufosinate	<0.050, <0.050, <0.050 [<0.050]	<0.4	
	Glufosinate propanoic acid	<0.050, <0.050, <0.050 [<0.050]	<0.1	
	N-acetylglufosinate	<0.050, <0.050, <0.050 [<0.050]	<0.1	

[1] Triplicate subsamples of each sample were analyzed. The LOQ was 0.05 ppm for each analyte in seed, meal, and refined oil, and 0.10 ppm for each analyte in hulls.
[2] Processing Factor = [Average measured residue for analyte in the processed fraction] / [Average measured residue for analyte in the RAC].
[3] Median processing factors are not applicable as only one trial was conducted.

Corn

A corn processing study was not submitted as part of the label amendment request. However, acceptable corn and soybean processing studies have been reviewed previously (D219069, M. Rodriguez, 3/7/1996; D227386, M. Rodriguez, 8/26/1996). Those studies showed no residue concentration in any processed corn commodity except for aspirated grain fractions (AGF), where a concentration factor of 12X was determined for corn AGF. For soybean AGF, a concentration factor of 9X was determined. The established AGF tolerance of 25 ppm was derived from the product of the corn AGF processing factor (12X) and the soybean seed tolerance (2.0 ppm).

Conclusions

The soybean processing studies indicate that glufosinate residues concentrate in soybean hulls. The recommended tolerance for a processed commodity is determined as the product of the highest average field trial (HAFT) value and the median concentration factor. Considering the concentration factor of 11.3X from Table 9 and the previously determined value of 2.66X (D219069, M. Rodriguez, 3/7/1996), the appropriate tolerance level for soybean hulls may be determined as: median CF x HAFT = 6.98 x 1.44 ppm = 10 ppm. No changes are needed to the established grain aspirated fractions tolerance of 25 ppm.

Meat, Milk, Poultry and Eggs

The current action has the potential to increase glufosinate ammonium residues in livestock feedstuffs from field corn, sweet corn, soybean, and almond. To determine if the proposed label

changes or 6(a)(2) data trigger a need for higher tolerances for livestock commodities, HED updated the dietary burden according to OECD methods, including the most recent residue data. Thus, More Balanced Diets (MBDs) were determined using the Dietary Burden Calculator PMRA v.2.8, which is based on the Guidance Document on Residues in Livestock, 04-SEP-2013 (OECD ENV/JM/MONO(2013)8). Table 10 summarizes the glufosinate ammonium MBDs determined for beef and dairy cattle, poultry, and swine.

Table 10. Dietary Burden and Livestock AR Calculations for Glufosinate Ammonium.

More Balanced Diet (MBD)

Crop	Commodity	Type	Residue		%DM	%Diet	Dietary Contribution ppm
			ppm	input			
Beef Cattle							
Corn, field	Stover	R	3.9[a]	HAFT	83	15	0.70
Grain	Aspirated grain fractions	CC	3.1[b]	Median	85	5	0.18
Beet, sugar	Molasses	CC	1.6[c]	Median	75	10	0.21
Corn, field	Milled byproducts	CC	0.03[a]	Median	85	50	0.02
Corn, field	Grain	CC	0.03[a]	Median	88	15	0.005
Soybean	Seed	PC	0.26[a]	Median	89	5	0.01
Total	**NA**	**NA**	**NA**	**NA**	**NA**	**100**	**1.14**
Dairy Cattle							
Corn, field	Stover	R	3.9[a]	HAFT	83	15	0.70
Corn, sweet	Stover	R	3.7[d]	HAFT	83	15	0.67
Corn, field	Forage	R	1.4[a]	HAFT	40	15	0.53
Beet, sugar	Molasses	CC	1.6[c]	Median	75	10	0.21
Corn, sweet	Cannery waste	CC	0.34[d]	Median	30	10	0.11
Corn, field	Milled byproducts	CC	0.03[a]	Median	85	25	0.009
Cotton	Undelinted seed	PC	1.1[e]	Median	88	10	0.13
Total	**NA**	**NA**	**NA**	**NA**	**NA**	**100**	**2.36**
Poultry							
Corn, field	Grain	CC	0.03[a]	Median	88	75	0.02
Soybean	Seed	PC	0.26[a]	Median	89	20	0.05
Untreated feed	NA	NA	NA	NA	NA	5	0
Total	**NA**	**NA**	**NA**	**NA**	**NA**	**100**	**0.07**
Swine							
Corn, field	Grain	CC	0.03[a]	Median	88	85	0.03
Soybean	Seed	PC	0.26[a]	Median	89	15	0.04
Total	**NA**	**NA**	**NA**	**NA**	**NA**	**100**	**0.06**

[a] This memo: see Appendix C for soybean seed; field corn grain, forage and stover median and HAFT values. Soybean hulls: 11.3 (CF) X 0.26 ppm = 2.9 ppm; soybean meal: 0.4 (CF) X 0.26 ppm = 0.10 ppm.

[b] D227386, M.I. Rodriguez, 26-AUG-1996. Max AGF CF = 12x. AR = CF X median soybean residue = 12 X 0.26 ppm = 3.1 ppm.

[c] D257682, T. Bloem, 09-JUL-1999. Molasses CF = 6.8X. 6.8 x 0.24 ppm (Mean sugar beet residue) = 1.6 ppm. Dried pulp: 0.6 x 0.24 ppm = 0.14 ppm.

[d] D372625, I. Negron-Encarnacion, 31-AUG-2010. Cannery waste residue translated from forage.

[e] D271110, T. Bloem, 20-JUN-2002 [45089303.der.wpd] cottonseed avg = 1.1 ppm; cotton gin byproduct avg = 3.76 ppm. [45204406.der.wpd]

Established tolerances for livestock commodities are based on maximum theoretical dietary burdens (MTDBs) calculated using tolerance level residues and methodologies followed in 2002 (D271110, T. Bloem, 20-JUN-2002). Lower dietary burden estimates identified as maximum reasonably balanced diets (MRBDs) were determined following revisions to livestock dietary procedures in June 2008 (D372625, I. Negron-Encarnacion, 31-AUG-2010). Table 11 provides a comparison of the MTDB, MRBD and MBD estimates for glufosinate ammonium, demonstrating that current dietary burden estimates are considerably lower than those used to determine the established livestock tolerances.

Table 11. Comparison of MTDB, MRBD, and MBD Estimates for Glufosinate Ammonium.

Animal	MTDB (JUN 2002) (ppm)	MRBD (AUG 2010) (ppm)	MBD (this review) (ppm)
Beef Cattle	15.4	6.2	1.1
Dairy Cattle	15.2	4.4	2.4
Poultry	3.3	0.81	0.07
Swine	8.9	0.63	0.06

Conclusions: Because the dietary burdens have not increased from those used for livestock commodity tolerance determination, HED concludes that the established livestock tolerances for ruminants and poultry remain appropriate.

International Harmonization

Appendix B lists a comparison of the tolerances and MRLs for the US, Canada, and Codex for crops relevant to the current action. The levels are not harmonized for the following: canola, seed; corn, grain (field and sweet); and tree nuts.

In cases where the US tolerance is lower than the corresponding MRL, HED frequently recommends increasing the US tolerance to match the MRL of international authorities. Thus, HED recommends increasing the canola, seed tolerance to 3.0 ppm. For tree nuts, field and sweet corn grain, harmonization is not possible as the US tolerances are higher than the corresponding MRLs established by Canada and Codex.

Analytical Reference Standards

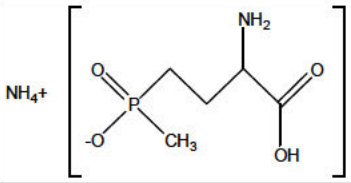
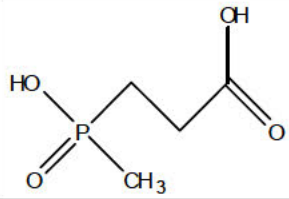
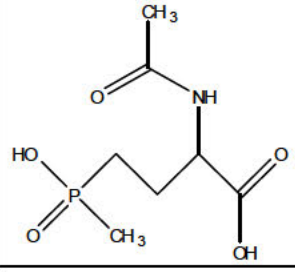
Analytical standards for residues of concern for glufosinate ammonium are presently up to date and available at the EPA National Pesticide Repository, as indicated in the table below (electronic communication with Gregory Verdin on 02/15/2017). The registrant must replenish supplies of these standards prior to expiration.

Chemical	Expiration Date
Glufosinate ammonium (GA)	4/9/25
3-(hydroxymethylphosphinyl) propanoic acid (MPP)	9/29/21
2-(acetylamino)-4-(hydroxymethyl phosphinyl) butanoic acid (NAG)	11/30/17

The Analytical Chemistry Branch in Ft. Meade is the owner of the repository. The address to submit standards is below. The full 9 digit zip code is mandatory or the mail will be returned to the sender.

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

Appendix A. Chemical Structure and Nomenclature for Glufosinate Ammonium and Residues of Concern

TABLE A. Test Compound Nomenclature.	
Compound	
Common name	Glufosinate ammonium
Company experimental name	AE F039866, HOE 039866
IUPAC name	ammonium (2*RS*)-2-amino-4-(methylphosphinato)butyric acid
CAS name	2-amino-4-(hydroxymethylphosphinyl)butanoic acid monoammonium salt
CAS registry number	77182-82-2
Compound	
Common name	Glu-PPA, AE F061517, Glufosinate propanoic acid, HOE 061517, MPP
Chemical name	3-methylphosphinico-propionic acid or 3-(hydroxymethylphosphinyl) propanoic acid
Compound	
Common name	Glu-NAG, AE F085355, N-acetylglufosinate, HOE 099730, NAG
Chemical name	2-(acetylamino)-4-(hydroxymethyl phosphinyl) butanoic acid

Appendix B. Glufosinate Ammonium International Residue Limits Table

Glufosinate Ammonium (PC Code 128850)

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US		Canada	Mexico[2]	Codex
40 CFR 180.473 Plant and Livestock: glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents		ammonium(±)-2-amino-4-(hydroxymethylphosphinyl)butanoate, including the metabolite propanoic acid, 3-(hydroxymethylphosphinyl)		Sum of glufosinate-ammonium, 3-[hydroxy(methyl)phosphinoyl]propionic acid and N-acetyl-glufosinate, calculated as glufosinate (free acid).
Commodity[1]	*Tolerance (ppm) /Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[2]	Codex
Canola, meal	1.1	--		--
Canola, seed	0.40	3		1.5
Corn, field, forage	4.0	--		--
Corn, field, grain	0.20	0.2		0.1
Corn, field, stover	6.0	--		8
Corn, sweet, forage	1.5	--		--
Corn, sweet, K+CWHR	0.30	0.2		--
Corn, sweet, stover	6.0	--		--
Soybean, hulls	10	--		--
Soybean, seed	2.0	2		2
Nut, tree, group 14-12	0.50	0.1		0.1

[1] Includes only commodities of interest for this action. US Tolerance values are either those established or those supported by data review.

[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

Appendix C. OECD MRL Calculation Procedure Results

Glufosinate ammonium
Pistachio
USA
3 x 0.5 lb ai/A, 14-day PHI

Total number of data (n)	6
Percentage of censored data	50%
Number of non-censored data	3
Lowest residue	0.030
Highest residue	0.230
Median residue	0.056
Mean	0.097
Standard deviation (SD)	0.088
Correction factor for censoring (CF)	0.667

Proposed MRL estimate

- Highest residue	0.230
- Mean + 4 SD	0.447
- CF x 3 Mean	0.194
Unrounded MRL	0.447
Rounded MRL	**0.5**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
< 0.03	3
0.081	1
0.18	1
0.23	1

Glufosinate ammonium
Soybean Seed
USA
2 x 0.8 lb ai/A, 70-day PHI

Total number of data (n)	21
Percentage of censored data	0%
Number of non-censored data	21
Lowest residue	0.057
Highest residue	1.440
Median residue	0.261
Mean	0.399
Standard deviation (SD)	0.350
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	1.440
- Mean + 4 SD	1.797
- CF x 3 Mean	1.196
Unrounded MRL	1.797
Rounded MRL	**2**

Residues (mg/kg)	n
0.057	1
0.0733	1
0.0859	1
0.11	1
0.111	1
0.121	1
0.143	1
0.155	1
0.222	1
0.257	1
0.261	1
0.302	1
0.366	1
0.559	1
0.56	1
0.57	1
0.652	1
0.654	1
0.815	1
0.855	1
1.44	1

Glufosinate ammonium
Field corn grain
USA
1.6 lb ai/A, 70-day PHI

Total number of data (n)	18
Percentage of censored data	56%
Number of non-censored data	8
Lowest residue	0.030
Highest residue	0.068
Median residue	0.030
Mean	0.039
Standard deviation (SD)	0.014
Correction factor for censoring (CF)	0.630

Proposed MRL estimate

- Highest residue	0.068
- Mean + 4 SD	0.095
- CF x 3 Mean	0.073
Unrounded MRL	0.095
Rounded MRL	**0.1**

High uncertainty of MRL estimate.
[High level of censoring]

Residues (mg/kg)	n
< 0.03	10
0.0305	1
0.0315	1
0.0354	1
0.0532	1
0.0547	1
0.0595	1
0.0654	1
0.0679	1

Glufosinate ammonium
Field corn forage
USA
1.6 lb ai/A, 60-day PHI

Total number of data (n)	18
Percentage of censored data	0%
Number of non-censored data	18
Lowest residue	0.034
Highest residue	1.420
Median residue	0.273
Mean	0.410
Standard deviation (SD)	0.423
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	1.420
- Mean + 4 SD	2.102
- CF x 3 Mean	1.230
Unrounded MRL	2.102
Rounded MRL	**3**

Residues (mg/kg)	n
0.0338	1
0.0691	1
0.102	1
0.115	1
0.119	1
0.14	1
0.231	1
0.244	1
0.271	1
0.274	1
0.308	1
0.332	1
0.366	1
0.412	1
0.532	1
1.08	1
1.33	1
1.42	1

Glufosinate ammonium
Field corn stover
USA
1.6 lb ai/A, 70-day PHI

Total number of data (n)	18
Percentage of censored data	0%
Number of non-censored data	18
Lowest residue	0.030
Highest residue	3.920
Median residue	0.374
Mean	0.620
Standard deviation (SD)	0.886
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	3.920
- Mean + 4 SD	4.165
- CF x 3 Mean	1.859
Unrounded MRL	4.165
Rounded MRL	**5**

Residues (mg/kg)	n
0.0303	1
0.081	1
0.0964	1
0.0993	1
0.16	1
0.169	1
0.192	1
0.248	1
0.253	1
0.494	1
0.585	1
0.628	1
0.642	1
0.688	1
0.788	1
0.979	1
1.1	1
3.92	1